

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<b>UNITED STATES OF AMERICA</b>	:	
<i>ex rel. DONALD R. GALMINES, et al.,</i>	:	<b>CIVIL ACTION</b>
<i>Plaintiffs,</i>	:	
	:	
<b>v.</b>	:	
	:	
<b>NOVARTIS PHARMACEUTICALS</b>	:	<b>No. 06-3213</b>
<b>CORPORATION,</b>	:	
<i>Defendant.</i>	:	

**MEMORANDUM**

PRATTER, J.

AUGUST 19, 2015

Mr. Galmines brings this *qui tam* action against Novartis Pharmaceuticals Corporation (“Novartis”) under the False Claims Act, 31 U.S.C. §§ 3729, et seq., and the laws of several states. Mr. Galmines asserts that Novartis engaged in “off-label” marketing for the drug Elidel, encouraging physicians to prescribe Elidel for purposes for which the FDA had not approved Elidel.<sup>1</sup> This marketing campaign resulted in submissions to the Government of false claims for reimbursement for the unapproved prescriptions of Elidel, including Medicare and Medicaid. Mr. Galmines also alleges that Novartis violated state “anti-kickback” statutes by providing various rewards to physicians who prescribed high volumes of Elidel.

Mr. Galmines now seeks to depose Alex Gorsky, the former CEO of Novartis, and the current Chairman and CEO of Johnson & Johnson. Mr. Gorsky has moved to quash the subpoena served upon him seeking his testimony at a deposition. Mr. Gorsky argues that his motion should be granted because, pursuant Federal Rule of Civil Procedure 45(d)(3)(A), the deposition would pose an undue burden upon him, requiring the Court to quash the subpoena. Moreover, Mr.

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<sup>1</sup> Specifically, Mr. Galmines alleges that Novartis marketed Elidel, an eczema drug, for unapproved uses such as first-line use, infant use, preventive use, and continuous use.

Gorsky asserts that the Court should prohibit the deposition pursuant Federal Rule 26(b)(2)(C), which provides that the Court must limit discovery when “the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive,” or, more generally, when “the burden or expense of the proposed discovery outweighs its likely benefit.” Mr. Gorsky asserts that because he lacks personal and superior unique knowledge of the facts alleged and because the information sought could be obtained from lower level employees or through less burdensome means, his Motion to Quash should be granted pursuant the “apex doctrine”.

The “apex doctrine” is an analytical framework used by courts in assessing whether to permit the depositions of individuals at the “apex” of corporations and other entities. The doctrine recognizes that depositions of high-level officers severely burdens those officers and the entities they represent, and that adversaries might use this severe burden to their unfair advantage. *See In re Tylenol (Acetaminophen) Mktg., Sales Practices & Products Liab. Litig.*, No. 2:13-MD-02436, 2014 WL 3035791, at \*2 (E.D. Pa. July 1, 2014) (“Depositions of high level corporate executives may be duplicative, cumulative and burdensome where the person sought to be deposed has no personal knowledge of the events in dispute.”)(citing *Harris v. Computer Assocs. Int’l, Inc.*, 204 F.R.D. 44, 46 (E.D.N.Y. 2001)); *Performance Sales & Mktg. LLC v. Lowe’s Companies, Inc.*, No. 5:07-CV-00140-RLV, 2012 WL 4061680, at \*3-4 (W.D.N.C. Sept. 14, 2012) (“The ‘apex doctrine,’ rooted in Federal Rule of Civil Procedure 26, was developed as an aid in ensuring that the liberal rules of procedure for depositions are used only for their intended purpose and not as a litigation tactic to create undue leverage by harassing the opposition or inflating its discovery costs.”). The doctrine thus requires courts to consider whether this severe burden is warranted by the likely benefit of the proposed discovery. *See Fed. R. Civ. P. 26(b)(2)(C)* (“[T]he court must limit the frequency or extent of discovery otherwise

allowed by these rules or by local rule if it determines that . . . the burden or expense of the proposed discovery outweighs its likely benefit.”). To aid in this analysis, the apex doctrine instructs courts to consider whether the high-level official has personal or superior unique knowledge of the facts alleged and whether the information could be obtained from lower level employees or through less burdensome means. *In re Tylenol*, 2014 WL 3035791, at \*3.

The parties dispute which party should bear the burden under the apex doctrine. The apex doctrine does not represent an exception to the rule that a party seeking to quash a subpoena bears the “heavy burden” of demonstrating that the subpoena represents an undue burden. *See Frank Brunckhorst Co. v. Ihm*, No. MISC. 12-0217, 2012 WL 5250399, at \*4 (E.D. Pa. Oct. 23, 2012). The apex doctrine is merely a tool for guiding the Court’s analysis in determining whether to limit discovery under Rule 26(b)(2)(C) because the discovery can be obtained from some other source that is more convenient, less burdensome, or less expensive. As such, the party seeking to quash the subpoena still bears the burden of persuasion. The apex doctrine does, however, apply a rebuttable presumption that a high-level official’s deposition represents a significant burden upon the deponent and that this burden is undue absent the two factors set forth in the apex doctrine, which go to the lack of a more convenient, less burdensome, and less expensive alternative. *See Performance Sales & Mktg.*, 2012 WL 4061680, at \*3-4 (“Put simply, the apex doctrine is the application of the rebuttable presumption that the deposition of a high-ranking corporate executive either violates Rule 26(b)(2)(C)’s proportionality standard or, on a party’s motion for a protective order, constitutes ‘good cause’ for such an order as an ‘annoyance’ or ‘undue burden’ within the meaning of Rule 26(c)(1). Should the deposing party fail to overcome this presumption, the court must then limit or even prohibit the deposition.”).

Here, Mr. Gorsky has asserted that he is a high-level official and that, per the two factors of the apex doctrine, his deposition should be quashed because it represents an undue burden

upon him and the corporation he represents. More specifically, Mr. Gorsky asserts that “more convenient, less burdensome, or less expensive” alternatives exist for obtaining the sought discovery. *See* Fed. R. Civ. P. 26(b)(2)(C)(i). Mr. Galmines, on the other hand, has failed to articulate the need for Mr. Gorsky’s deposition, beyond the generic assertions that Mr. Gorsky was involved in the marketing of Elidel and in developing the corporate response to the Food and Drug Administration’s decision to place a “black box warning” on Elidel. In support of his position, Mr. Galmines has filed with the Court a PowerPoint slide that Mr. Gorsky allegedly reviewed. The slide displays the percentage of Elidel sales for off-label uses. Mr. Galmines has also submitted an email from Mr. Gorsky to a business associate in which Mr. Gorsky recommends editing that PowerPoint slide by changing the phrase “off-label sales” to “other sales.”

Mr. Galmines has not articulated how Mr. Gorsky’s statement in this email ties to any material matter in dispute. *Cf. Reif v. CNA*, 248 F.R.D. 448, 454 (E.D. Pa. 2008) (“The Reifs have not demonstrated a nexus between [the CEO’s] statement and lower level management’s decision . . . .”). More broadly, Mr. Galmines has not specifically tied any information sought from Mr. Gorsky to any material matter in the case. *Cf. Folwell v. Hernandez*, 210 F.R.D. 169, 174 (M.D.N.C. 2002) (“[T]he oral deposition of a high level corporate executive should not be freely granted when the subject of the deposition will be only remotely relevant to the issues of the case.”). This failure to articulate a specific and substantiated argument supporting the need for Mr. Gorsky’s deposition distinguishes this case from *In re Tylenol*, where Judge Stengel denied a motion to quash because “documents, which have been produced by the defendants during discovery, show very clearly that [the high-ranking executive] was actively involved in decision making regarding the marketing and product development of Tylenol products . . . . They also indicate that [he] has knowledge that is unique to him and which could not be obtained

through the depositions of those other . . . employees not quite at the ‘apex.’” *See* 2014 WL 3035791, at \*3. Mr. Galmines has not articulated why the information sought (whatever, specifically, it may be) could not be obtained from lower level employees or through less burdensome means. This silence is particularly deafening in light of the posture of discovery in this case: Mr. Galmines has deposed six corporate representatives of Novartis and 12 fact witnesses. Despite these multitude of depositions, the Court has not been made aware of any efforts to ascertain from these deponents the extent of Mr. Gorsky’s personal involvement in the alleged actions. *Cf. Reif*, 248 F.R.D. at 454 (granting CEO’s Motion to Quash where “[t]he depositions, thus far, have failed to demonstrate the deponents lack the information, especially when the pertinent questions have not been asked”).

The Court will therefore grant the Motion to Quash because “the burden or expense of the proposed discovery outweighs its likely benefit.” *See* Fed. R. Civ. P. 26(b)(2)(C). However, the Court will grant it without prejudice, such that Mr. Galmines can seek reconsideration of the Court’s determination. Any effort for reconsideration, however, should include (1) greater specificity in the link between the sought information and a material matter in dispute; and (2) a proposal for a less burdensome manner of obtaining the sought information. This effort for reconsideration should first be shared with counsel for Mr. Gorsky before seeking reconsideration from the Court. An appropriate order follows.

BY THE COURT:

S/Gene E.K. Pratter  
GENE E.K. PRATTER  
United States District Judge

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**O R D E R**

**AND NOW**, this 19<sup>th</sup> day of August, 2015, upon consideration of Mr. Gorsky's Motion to Quash (Docket No. 131), Mr. Galmines's Response in Opposition thereto (Doc. No. 133), Mr. Gorsky's Reply (Doc. No. 135), and the phone conference held with the litigants on August 4, 2015, the Motion to Quash is **GRANTED** in accordance with the accompanying Memorandum.

BY THE COURT:

S/Gene E.K. Pratter  
GENE E.K. PRATTER  
United States District Judge